

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: WAVE 8 CASES ON ATTACHED EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**PLAINTIFFS’ MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE OR LIMIT
CERTAIN OPINIONS OF ETHICON, INC. AND JOHNSON & JOHNSON’S EXPERT
WITNESS DEBRA FROMER, M.D.**

Pursuant to Federal Rules of Evidence 702, 403, and 104, Plaintiffs respectfully request that this Court exclude or, alternatively, limit certain opinions and/or testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson’s expert Debra Fromer, M.D. (“Dr. Fromer”) concerning Wave 8 Plaintiffs implanted with Ethicon’s pelvic organ prolapse and stress urinary incontinence device for which Dr. Fromer is either unqualified to offer or utilized unreliable methods in rendering her opinions.

INTRODUCTION

The Wave 8 Plaintiffs hereby adopt and incorporate by reference the *Daubert* motion and memorandum filed against Dr. Fromer in Wave 1, Dkt. 2081 (motion), 2084 (memorandum in support), including all arguments that are generally applicable regardless of product type that were not the subject of Dr. Fromer’s Wave 1 expert report. For example, this Court previously excluded Dr. Fromer’s warning opinions based on her lack of sufficient qualifications to offer those opinions. Any new argument not previously adjudicated, are set forth in detail below.

In her Wave 8 report, Dr. Fromer provides sweeping, general opinions concerning the history of treatment of pelvic organ prolapse, the development and design of the Prolift+M devices, the efficacy and safety of alternative devices and procedures, qualities and properties of polypropylene and other synthetic graft materials, her own unsupported personal experience using these devices, and the accuracy and adequacy of the Prolift+M Instructions for Use (“IFU”). However, Dr. Fromer is unqualified to offer many of these opinions or fails to demonstrate that her opinions are based on reliable methodologies. Accordingly, Plaintiffs move to limit or exclude Dr. Fromer’s opinions pursuant to the *Daubert* standard.

LEGAL STANDARD

For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. It is known and understood that the admissibility of expert testimony is governed by the Federal Rules of Evidence, including but not limited to Rules 702, 403 and 104.¹ The trial judge acts as a gatekeeper for scientific, technical, and other specialized knowledge.²

ARGUMENT

Dr. Fromer is board certified in urology and female pelvic medicine and reconstructive surgery who practices in New York.³ However, Dr. Fromer’s medical training in the fields of urology and female pelvic medicine does not automatically render her opinions on other ancillary issues admissible.⁴ Indeed, to be admissible each individual opinion she offers must

¹ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

² See *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 587 (1993); *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 141 (1999).

³ Fromer report attached hereto as Exhibit B and Fromer Curriculum Vitae attached hereto as Exhibit C.

⁴ See *Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (federal law governs admissibility of expert testimony).

satisfy the requirements of the Federal Rules of Evidence.⁵ As a threshold matter, an expert witness “must have ‘knowledge, skill, experience, training, or education’ in the subject area in which he will testify.”⁶ In the context of Rule 702, knowledge “connotes more than subjective belief or unsupported speculation.”⁷ Trial courts must ensure that a purported expert witness “is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise.*”⁸ One of the most fundamental prerequisites to admission of an expert’s opinion is that the opinion be related to that expert’s specialized knowledge.⁹

Dr. Fromer’s opinions must also be based upon reliable and proper methods.¹⁰ As this Court has recognized:

Just because an expert may be “qualified . . . by knowledge, skill, experience, training or education” does not necessarily mean that the opinion that the expert offers is “the product of reliable principles and methods” or that the expert “has reliably applied the principles and methods to the facts of the case.”¹¹

The burden is on Ethicon to show that *each* of Dr. Fromer’s opinions has a reliable foundation based on stated principles and methods.¹² Opinions not within Dr. Fromer’s area of expertise, or not the product of reliable principles and methods, should be excluded.

I. DR. FROMER IS UNQUALIFIED TO OFFER WARNING OPINIONS AND THOSE OPINIONS ARE UNRELIABLE

In the context of Dr. Fromer’s Wave 1 TVT and Prolift expert report, this Court has already precluded Dr. Fromer from offering warning opinions or opinions concerning the adequacy of IFUs, holding that “[w]hile an expert who is a urologist may testify about the

⁵ See, e.g., *Gen. Elec. Co.*, 522 U.S. at 142; see also *Daubert*, 509 U.S. at 579.

⁶ *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013) (quoting FED. R. EVID. 702).

⁷ *Daubert*, 509 U.S. at 590.

⁸ *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).

⁹ See, e.g., *U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).

¹⁰ See *Coleman v. Union Carbide Corp.*, 2013 U.S. Dist. LEXIS 140613, * 50 (S.D. W. Va. 2013) (holding that expert testimony must be reliable and relevant to be admissible).

¹¹ *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D. W. Va. 2013).

¹² See *Daubert*, 509 U.S. at 597.

specific risks of implanting mesh and whether those risks appeared in the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.”¹³ Despite this, in her Wave 8 report, Dr. Fromer continues to offer warning opinions but has not demonstrated that she has gained sufficient additional experience since the Court’s Wave 1 order other than her involvement in a single 2018 litigation-driven publication that compared the “the pertinent role the IFU plays in mesh related litigation” to use of the IFU in a small pool of physicians surveyed by Dr. Fromer and her colleagues in 2018. As an initial matter, publishing results from a single survey study concerning the utilization of IFUs by a small group of physicians does not provide Dr. Fromer with sufficient additional expertise to offer these opinions in Wave 8.¹⁴

Additionally, Dr. Fromer should also be prohibited from rendering opinions based on her recent survey that are not actually supported by the study’s results. In her 2018 article,¹⁵ Dr. Fromer and her colleagues report on the results of a survey they sent to 7,212 physicians. The survey was limited¹⁶ to the following questions:

¹³ Memorandum Opinion and Order (*Daubert* Motion re: Debra Fromer, M.D.) [ECF No. 2702] at 7-8, attached hereto as Exhibit D. (citing *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015).

¹⁴ Kirkpatrick DO, et al. *Transvaginal Mesh Placement and the Instructions for Use: A Survey of North American Urologists*, *Urology Practice* (2018) attached as Exhibit E.

¹⁵ *Id.*

¹⁶ *Id.* at 10 (Table 1)

Table 1: Survey Questions

Q1	What type of provider are you?
Q2	Approximately how many polypropylene mesh midurethral sling kits have you implanted?
Q3	Approximately how many polypropylene mesh midurethral sling kits have you implanted this past year?
Q4	Approximately how many polypropylene mesh kits for prolapse have you implanted?
Q5	Approximately how many polypropylene mesh kits for prolapse have you implanted this past year?
Q6	What type of polypropylene mesh midurethral sling kits have you utilized?
Q7	If you have utilized a retropubic polypropylene mesh midurethral sling kit(s), what technique have you utilized for placement?
Q8	If you have utilized a trans-obturator polypropylene mesh midurethral sling kit(s), what technique have you utilized for placement?
Q9	Have you ever read the Instructions for Use manual on a polypropylene mesh midurethral sling kit?
Q10	If you answered yes above, with what frequency have you read it?
Q11	If you answered "until comfortable" above, approximately how many mesh placements did you perform until comfortable?
Q12	Have you ever read the Instructions for Use manual on a polypropylene mesh prolapse kit?
Q13	If you answered yes above, with what frequency have you read it?
Q14	If you answered "until comfortable" above, approximately how many mesh placements did you perform until comfortable?

Only 314 physicians responded. After excluding those physicians who never implanted either of these devices, the survey results showed that, for physicians who had ever implanted pelvic organ prolapse kits or midurethral slings, 76.9% (POP kits) and 63.1% (SUI kits) responded that they had read the IFU at least once prior to implanting these devices into their patients.¹⁷ Thus, the survey results showed that the vast majority of implanting physicians read the IFUs at least once before implanting these devices into their patients. Nevertheless, Dr. Fromer opines that these results "suggest that implanting physicians rely more heavily on other information such as intensive training, a robust body of medical literature, and medical conferences, rather than the IFU, in planning, consent process and surgical technique."¹⁸ However, this opinion is unsupported by the survey results which - as shown above - never even sought to determine what potential other sources of information these physicians relied upon or the degree to which they relied upon any one source of information over another. In other words, Dr. Fromer simply speculates or asks the Court to "take the expert's word for it."¹⁹

¹⁷ *Id.* at 5 (Not surprisingly, Dr. Fromer – an Ethicon paid expert witness – and colleagues attempt to undermine these results by only highlighting the percentage of physicians who responded that they had never read the IFUs prior to implanting POP or SUI kits in their patients (23.1% and 64.4% respectively).

¹⁸ Fromer Wave 8 Report at 60 attached as Exhibit B.

¹⁹ *Pugh v. Louisville Ladder, Inc.* 361 Fed. Appx. 448, 452 (4th Cir. 2010) (internal citations omitted).

Instead, the Court should conclude there is “too great an analytical gap” to render this opinion reliable.²⁰

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court exclude the above opinion testimony from Debra Fromer, M.D.,

Respectfully submitted,

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²⁰ *Id.* at 454, fn.4